

## REMARKS

As requested in the Amendment mailed August 5, 2004, the Examiner's attention is directed to the Information Disclosure Statement mailed September 3, 2003 and to the Supplemental Information Disclosure Statement mailed September 30, 2003, neither of which appears to have been considered by the Examiner. Copies of such Information Disclosure Statements, and the return postcard stamped by the Patent and Trademark Office on September 8, 2003 pertaining to the Information Disclosure Statement and the return postcard stamped by the Patent and Trademark Office on October 3, 2003 pertaining to the Supplemental Information Disclosure Statement, are enclosed herewith. Applicants again request that the Examiner consider such Information Disclosure Statements and indicate such consideration in the next action.

Claims 1-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Barath (U.S. Patent No. 5,196,024), Vigil et al. (U.S. Patent No. 5,320,634), Kaplan et al. (U.S. Patent No. 5,336,178), and further in view of Klein (U.S. Patent No. 5,863,284). Reconsideration of these claims is respectfully requested.

Barath discloses a cutting balloon catheter having a catheter shaft (1), and a lumen with an inflatable balloon (2), in its inflated state, at the distal end. In the catheter shaft, there is a central lumen (3) and a coaxial lumen (4). The central lumen accommodates the catheter guide wire and provides a channel for injection of the contrast material. The coaxial lumen serves to inflate the balloon through side holes (5). Sharp longitudinal processes or cutting edges (6) protrude parallel with the longitudinal axis of the surface of the balloon. Col. 3, line 62 through Col. 4, line 3. The balloon shown in FIG. 2 is inflated (2) and the cutting edges (6) penetrate into the vessel wall (7, 8) making longitudinal cuts with sharp margins (11) in the vessel wall. Col. 4, lines 18-21. FIG. 7 and its cut-out FIG. 8 show a metallic cutting edge (6) which is sitting on a metallic plate (13). The metallic plate and edges are discrete sections and mounted onto the balloon surface in a row parallel with the longitudinal axis of the balloon, thereby providing articulation to the device. The edges are covered by folds (14) of the balloon in the deflated state. Col. 4, lines 54-61. FIG. 14 shows an embodiment in which the cutting edges are formed of specially shaped wires (19) sitting in grooves (14) on the balloon (2) surface. As shown in FIG. 15, the distal ends (20) of the wires are fixed to the distal part of the catheter shaft (21) while the proximal end of the wire (22) goes underneath a ring (23) placed around the catheter

shaft (1). The wires can freely slide under the ring. The wires are not mounted in other places to the balloon surface allowing a free sliding longitudinal motion of the wires along the longitudinal axis of the balloon within the groove, upon inflation and deflation. Col. 5, lines 34-50.

Vigil et al. discloses a balloon catheter with seated cutting edges. Device 10 includes a balloon 12 positioned near the distal end 13 of a hollow catheter 14. Col. 3, lines 38-39.

Balloon 12 includes, as shown in FIG. 1, a plurality of substantially identical atherotomes 28a, 28b, 28c mounted on outer surface 18 of balloon 12 aligned along the longitudinal axis of catheter 14 and circumferentially equidistant from each adjacent atherotome. Col. 4, lines 8-12.

Kaplan et al. discloses an intravascular catheter for administering a therapeutic agent to a treatment site in the wall of a vessel. Col. 3, lines 51-54.

Klein discloses apparatus and methods for performing angioplasty, and particularly for the internal irradiation of the treated vessel, post-dilatation. Apparatus of the invention include catheters or catheter systems which employ a balloon to place radioactive sources in apposition with a vessel wall. The invention covers embodiments where the radioactive sources are directly attached to the balloon, embodiments where the radioactive sources are attached to a sleeve which in turn is slidably disposed about the balloon, and radioactive sources that are self supporting and slidably adjusted about the balloon. The sleeve attachment embodiments comprise both a balloon catheter and at least one radioactive source which is attached to or secured within a radiation-emitting sleeve catheter (RESC). Col. 9, lines 50-64. An alternative embodiment of a RESC 100 is illustrated in FIGS. 16-20A. RESC 100 is similar to RESC 10 of FIG. 1 except that RESC 10 includes eight radioactive elements 102. As shown in FIGS. 16 and 17, a standard PTCA balloon 108 is positioned within RESC 100. Balloon catheter 108 includes a balloon 110 which may be inflated to the configuration illustrated in FIG. 17 to radially deploy radioactive elements 102 against a vessel wall 112. Col. 16, line 65 to Col. 17, line 9. Initially, angioplasty is performed on a diseased area of the vessel as previously described in connection with FIG. 13, and the angioplasty balloon catheter is removed from the patient. RESC 100 is then positioned over the same (or another) angioplasty balloon catheter and introduced over the guidewire similarly to the procedure previously described in connection with FIG. 14. Col. 17, lines 48-55. Catheter system 164 of FIGS. 30 and 31 includes a balloon catheter 166 having a balloon 168. Secured around balloon 168 by an elastomeric sleeve 174 are a plurality of radiation emitting elements 176. Elastomeric sleeve 174 serves to secure radioactive elements

176 to balloon 168 and to maintain generally equal circumferential spacing between radioactive elements 176 when balloon 168 is inflated to place radioactive elements 176 in apposition to a vessel wall 178 as illustrated in FIG. 31. Col. 20, lines 2-14.

Amended Claim 1 is patentable by calling for a balloon catheter for performing an angioplasty procedure on a lesion in a vessel of the type set forth therein having, among other things, at least one flexible elongate element extending over the outer surface of the balloon from the proximal extremity to the distal extremity of the balloon, said flexible elongate element having a proximal extremity coupled to the catheter shaft proximal of the inflatable portion of the balloon and a distal extremity, an elastic member coupling the distal extremity of the flexible elongate element to the catheter shaft distal of the inflatable portion of the balloon for permitting the flexible elongate element to move radially outward as the balloon is inflated whereby expansion of the balloon causes movement of the flexible elongate element into engagement with the lesion to form a longitudinal channel in the lesion.

None of Barth, Vigil et al., Kaplan et al. or Klein discloses a balloon catheter having a flexible elongate element and an elastic member coupling the distal extremity of the flexible elongate element to the catheter shaft distal of the inflatable portion of the balloon for permitting the flexible elongate element to move radially outward as the balloon is inflated.

Claim 6 has been cancelled, without prejudice. Claims 2, 5, 7-15 and 20 depend from Claim 1 and are patentable for the same reasons as Claim 1 and by reason of the additional limitations called for therein.

Claim 21 is patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel of the type set forth therein having, among other things, at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon. None the cited references discloses at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon.

Claims 22-24 depend from Claim 21 and are patentable for the same reasons as Claim 20 and by reason of the additional limitations called for therein.

Claim 25 is patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel of the type set forth therein in which, among other things, at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material to permit stretching of the flexible elongate element during inflation of the balloon. None of the cited references discloses a balloon catheter of the type called for in Claim 24 in which at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material to permit stretching of the flexible elongate element during inflation of the balloon.

Claim 26-27 depend from Claim 25 and are patentable for the same reasons as Claim 24 and by reason of the additional limitations called for therein.

Claims 28-29 have been cancelled, without prejudice.

Claim 30 is patentable for the same reasons as Claim 1 by calling for a balloon catheter for performing medical procedure on a lesion in a vessel having, among other things, an elastic member for securing of the second extremity of the flexible elongate member to the catheter shaft for permitting the flexible elongate member to move radially outward as the balloon is inflated.


Claim 31 and new Claims 32-35 depend from Claim 30 and are patentable for the same reasons as Claim 30 and by reason of the additional limitations called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help

further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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